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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/526,134

10/19/2005

Maurice Goldman

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06/29/2009

GE HEALTHCARE, INC.

IP DEPARTMENT 101 CARNEGIE CENTER

PRINCETON, NJ 08540-6231

EXAMINER

SCHLIENTZ, LEAH H

ART UNIT

PAPER NUMBER

1618

MAIL DATE

DELIVERY MODE

06/29/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/526,134	Applicant(s) GOLDMAN ET AL.	
	Examiner Leah Schlientz	Art Unit 1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 June 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Acknowledgement of Receipt

Applicant's Response, filed 6/11/2009, in reply to the Office Action mailed 4/17/2009, is acknowledged and has been entered. Claims 1-11 are pending and are examined herein on the merits for patentability.

Response to Arguments

Any rejection or objection not reiterated herein has been withdrawn.

Applicant's arguments, with respect to the rejection(s) of claim(s) 1-11 under 35 USC 112, first paragraph, have been fully considered, but are not persuasive for reasons set forth hereinbelow. In addition, upon further consideration, a new ground(s) of rejection is made in view of Barkenmeyer et al. (*J. Magnetic Resonance*, 1996, p. 129-132).

Claim Rejections - 35 USC § 112

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to

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one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification as filed does not provide a description of the claimed hydrogenatable, unsaturated substrate compound required to make and use the contrast agent broadly claimed. There is no description provided regarding what type of specific chemical moieties are used to represent the substrate that would render such a compound to be useful as a contrast agent. There is very little predictability in the art concerning any undefined species which may represent a substrate compound and which chemical moiety would represent a substrate out of an almost unlimited number of chemical species which may be possible. The specification does not provide any guidance to the specific identity or physical/chemical structure of the variables which represent a substrate, and because the structures of these elements are undefined, it is unclear how Applicant envisaged suitable elements to satisfy the functional requirements of the substrate. While it is noted that the specification at published paragraph 0029 states that a hydrogenatable substrate "may be a material such as a para-hydrogenation substrate as discussed in WO99/24080, or its US equivalent United States Patent 6,574,495," such a statement does not provide a clear description of suitable substrate compounds. For example, an incorporation by reference must express a clear intent to incorporate by reference by using the words "incorporate" and "reference" (see 37 CFR 1.57(b)). In the instant case, no such statement exists, and thus there is no clear intent to incorporate by reference the subject matter that identifies a hydrogenatable, unsaturated substrate compound, and no adequate description of such a compound has been provided. A description of the

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identity of a suitable substrate compound is considered to be essential material to the method which is claimed. It is further noted that the Examples of the specification describe preparation of maleic acid, succinic acid and o-Acetyl lactic acid, such a limited disclosure of a two specific compounds does not provide adequate description for full scope of any and all "hydrogenatable substrate compounds," as claimed, and thus the claims are more broad than the enabling disclosure.

Applicant argues on page 8 of the Response that In the context of the claimed invention, one of skill in the art would understand what is meant by a "hydrogenatable, unsaturated substrate compound" as the terms "hydrogenatable" and "unsaturated" are known terms in the art. In addition, the substrate is further qualified in independent claim 1: "...wherein the substrate compound comprises imaging nuclei;" The term "imaging nuclei" is described on page 5, line 24 through page 6, line 2 of the Specification. Furthermore, the Specification references published document WO99124080 and its US equivalent 6,574,495 for examples of suitable hydrogenatable, unsaturated substrate compounds. Still further, based on the examples set forth on pages 22-24 of the Specification, one of skill in the art would understand that the hydrogenatable, unsaturated substrate compound will depend upon the desired contrast agent (*e.g.*, if maleic acid is the desired contrast agent, then the hydrogenatable, unsaturated substrate could be acetylenedicarboxylic acid; if succinic acid is the desired contrast agent, then the hydrogenatable, unsaturated substrate could be acetylenedicarboxylic acid or maleic acid). This is not found to be persuasive. While it is acknowledged that one would readily understand what is meant by the terms hydrogenatable, unsaturated,

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and imaging nuclei. However, Applicant has failed to provide an adequate description of what compounds are to be encompassed by the term substrate compound. While three specific contrast agents have been described, maleic acid, lactic acid or acetyl lactic acid, such a limited description of three compounds does not provide support of further compounds which Applicant envisaged that would be within the scope of any unsaturated compound, as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Barkenmeyer et al. (*J. Magnetic Resonance*, 1996, p. 129-132).

Barkenmeyer discloses that in a 400 MHz Varian spectrometer (VXR-400), parahydrogen was enriched to about 50% by passing ordinary hydrogen over charcoal in a U-tube cooled to 77 K in liquid nitrogen. This gas was bubbled into a solution, containing 3.1 ml CDC13, 20 mg of the catalyst [Rh(norbomadiene)(PPh₃)₂], and 100 μl of 1-hexyne or phenylacetylene. Samples were subjected to six pulse sequences. The field of the spectrometer would be a stationary magnetic field, and the pulses read on an oscillating field, as claimed. Enhanced ¹³C spectra are recorded. See pages 129-131. Regarding claims 8 and 10, Barkenmeyer discloses corresponding pulse

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sequences, see page 130, Figure 1. It is noted that the recitation of the intended use of the hydrogenated substrate as a contrast agent has not been given patentable weight to distinguish over Barkenmeyer because the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Since Barkenmeyer discloses the same method steps as those that are claimed, Barkenmeyer meets the claims.

Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leah Schlientz whose telephone number is 571-272-9928. The examiner can normally be reached on Monday - Friday 8 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hartley can be reached on 571-272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

LHS